

## **REMARKS/ARGUMENTS**

Currently amended claims 1, 5, 6 and 15 remain in the application, all other claims having been canceled.

Applicant respectfully requests that the Examiner withdraw the rejection of the claims in view of the amendments to the claims and the following remarks.

### **Specification**

The objection to the specification appears to be based on a mistake. Whereas the Examiner submits that reference numeral "23" is missing from the previous amendment, Applicant has attached hereto page 3 of its previous amendment which clearly shows that the numeral designation 23 was in fact included.

### **Claims Rejection – 35 U.S.C. § 103**

Claims 1-3, 5-7 and 15 are rejected as being unpatentable over Spence (4,783,321) in view of Lorenz (4,551,311) and Stolzman (5,631,311).

Applicant's invention provides an effective seal around a filtered vent of a sterilization container so that anything that passes from the exterior of the container into the interior of the container must pass through the filter to prevent any contaminants from entering the container. Applicant's invention, as fully disclosed in the specification and set forth in the pending claims, is characterized by its simplicity and elegance that provide an effective, safe, economic, and durable seal.

Spence '321 demonstrates, as did those references previously cited but no longer relied upon, that there are different patentable

combinations of elements for securing filter sheets to the vent of a sterilization container.

As will be demonstrated below, the Spence '321 arrangement of components for sealing a filter sheet to a sterilization container vent is quite different from that of Applicant's invention and, for all of its complication and numerous components, does not provide as effective and durable a seal as does Applicant.

Spence's arrangement for attaching and sealing a filter sheet to a sterilization container is best illustrated at Figs. 2 and 8. To the interior surface of the lid 24 are two generally circular, spaced-apart, upstanding flanges 36 and 37 that define a generally rectangular groove between them and above the interior surface. The filter 20 is secured within the rectangular space formed by flanges 36 and 37 by retainer securing flange 44 being inserted into the space between flanges 37 and 36 and "sandwiching" the filter paper therebetween. It is important to note that in addition to extending above the interior surface (as opposed to below as claimed by Applicant), the space between upstanding flanges 36 and 37 is rectangular with 90 degree angles and not "arcuate" and is not required or expected to contain a gasket of any kind.

Thus, where Spence teaches two exposed flanges standing above the plane of the interior surface of the lid, Applicant's invention (as claimed) calls for an arcuate recess formed in the interior surface of the vent planar member below the plane of that surface.

Where Spence teaches that the flanges 36 and 37, filter paper 20 and filter paper retainer 18 form a seal without the need for a gasket (see

Col. 5, lines 49–60), Applicant claims an arrangement of parts that includes a gasket and avoids the potential for tearing the filter paper.

The serious deficiency in Spence's arrangement of parts as described above is that the shearing action on the filter paper 20 when "sandwiched" between the upstanding flanges 36 and 37 and the depending sealing flange 44 is likely to tear the filter paper. Obviously, any damage to the sheet filter 20 compromises the effectiveness of the filter's ability to prevent the migration of contaminant into or out of the sterile container.

Furthermore, the construction of the Spence's lid including the upstanding flanges 36 and 37 is far more complex and, thus, expensive to manufacture and is exposed to damage as compared to Applicant's invention as claimed. Similarly, Spence's sealing flange is exposed and could easily be bent out of alignment.

Thus, whereas Spence teaches that the vent in the lid 24 is surrounded by upstanding concentric flanges that are readily vulnerable to being bent or damaged, Applicant, by contrast, claims a vent recess having a generally arcuate cross-section formed in the vent planar member by deformation of the vent planar member to create the vent recess below the interior surface of the vent planar member. Thus, where Spence teaches an upstanding exposed structure, Applicant teaches that the planar member in which the vent resides be deformed so as to create an arcuate recess that surrounds the vent. Clearly, the two structures are physically and functionally different, with Applicant's invention having the advantages of ease of manufacture and durability.

Similarly, the sealing flange 44 of Spence that is designed to be inserted into the groove between upstanding flanges 36 and 37 presents an unsupported member easily damaged in a way that would make alignment between the sealing flange 44 and the flanges 36 and 37 difficult if not impossible.

Lorenz fails to supply any of the elements of Applicant's claimed invention absent in Spence.

Thus, Applicant's invention, which allows for far greater ease of manufacture, also provides an environment for sealing the filter that does not threaten the integrity of the filter itself. In Applicant's invention as claimed, an arcuate-shaped relatively soft gasket is fully contained within the arcuate recess and covers essentially all of the surface of that recess so as to provide no sharp edges or corners that could damage the filter. Similarly, the filter cover ridge is also arcuate in shape so as to avoid any sharp corners that could penetrate and degrade the effectiveness of the seal.

Thus, Applicant's invention provides a simpler but more effective arrangement of components for retaining and sealing a filter in a sterilization container wherein the components are not exposed to easy damage or misalignment and where the filter is not exposed to elements that could cause it damage and compromise its integrity.

With reference specifically to claim 1, Spence fails to teach any of the following:

- (1) a vent recess having a generally arcuate cross-section formed in the vent planar member by deformation of the vent planar member to

create said arcuate vent recess on the interior surface of the vent planar member which recess extends below the plane of the interior surface and also creates a corresponding generally arcuate opposing protective ridge that extends above the plane of the exterior surface of the vent planar member wherein said recess and said ridge completely surround the container vent;

(2) a gasket having a generally arcuate cross-section secured wholly within said vent recess and in contact with substantially the entire concave surface of said vent recess whereby said gasket is protected against damage; and

(3) a generally planar filter cover that is disposed to move into engagement with the vent planer member and having a cover vent by which sterilization media can pass through said filter cover, said planar filter cover further comprising a generally accurate convex cover ridge formed in said filter cover by deformation thereof wherein said cover ridge completely surrounds said cover vent and wherein said cover ridge is coextensive with said vent recess and sized to at least partially fit into said vent recess, whereby when said vent recess and said cover ridge are aligned and said filter cover is operatively secured in place, a positive force is applied to said cover ridge forcing it toward and in engagement with said gasket in said vent recess, whereby said cover ridge is forced against said sheet filter which, in turn, is forced against said gasket whereby said cover ridge, said gasket and said vent recess form a particulate and fluid tight seal that surrounds both the container vent

and said cover vent which prevents fluid from entering or leaving the sterilization container through the seal so formed.

The proposed combination of Lorenz ('311) to Spence to add a gasket in the space between the upstanding flanges 36 and 37 is based on nothing more than hindsight. Spence specifically teaches a gasketless sealing structure such that the addition of a gasket has no place in Spence. The combination of Lorenz and/or Stolzman with the primary reference Spence is, in this case, specifically prohibited by *KSR International v. Teleflex Inc.* 550 U.S. \_\_\_\_ (2007) (KSR), where it states:

"[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness".

"As is clear from cases such as *Adams*, a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art."

"It can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." (Emphasis added.)

"See *Graham*, 383 U. S., at 36 (warning against a "temptation to read into the prior art the teachings of the invention in issue" and instructing courts to "guard against slipping into the use of hindsight" (quoting *Monroe Auto Equipment Co. v. Heckethorn Mfg. & Supply Co.*, 332 F. 2d 406, 412 (CA6 1964)))."

Because Spence specifically teaches an arrangement of parts that has as one of its "advantages" that a gasket is not required, there was nothing in Spence that "would have prompted a person of ordinary skill in the relevant field to combine the elements of the cited patents in the

way the claimed new invention does" to create a seal with a gasket. The rejection depends on a gasketless seal of Spence, together with parts from Lorenz and parts from Stolzman to reconstruct the Spence structure using those diverse parts to create a seal with a gasket where none existed or was intended or required. The very essence of the Spence invention would have to be discarded to justify adding a gasket.

If anything, Spence teaches away from Applicant's invention by teaching an arrangement of parts that do not require or accommodate a gasket and by teaching an arrangement of parts where a gasket that contacted essentially the entire surface of the "recess" would not be practical and would not work.

Furthermore, the rejection fails the TSM test, which is not dead.

In *Ortho-McNeil Pharma v Mylan*, 520 F.3d 1358 (Fed. Cir. 2008) the Federal Circuit made it clear that the TMS test still has its place. It states at page 1365:

"[Before] . . . KSR, the Federal Circuit endorsed a 'rigorous application' of the teaching, suggestion, or motivation (TSM) test. In KSR, the Supreme Court explained that a 'rigid' TSM test "'s incompatible with our precedents.' KSR, 127 S.Ct. at 1741. The Supreme Court explained its reason for castigating a 'rigid' TSM test: 'The obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents.' Id. Indeed a rigid requirement of reliance on written prior art or patent references would, as the Supreme Court noted, unduly confine the use of the knowledge and creativity within the grasp of an ordinarily skilled artisan. Id. at 1742."

" As this court has explained, however, a flexible TSM test remains the primary guarantor against a non-statutory hindsight analysis such as occurred in this case. In re Translogic Tech., Inc., 504 F.3d 1249, 1257 (Fed.Cir.2007) ('[A]s the Supreme Court suggests, a flexible approach [520 F.3d 1365] to the TSM test prevents hindsight and focuses on evidence before the time of invention.'). The TSM test, flexibly

applied, merely assures that the obviousness test proceeds on the basis of evidence — teachings, suggestions (a tellingly broad term), or motivations (an equally broad term) — that arise before the time of invention as the statute requires. As KSR requires, those teachings, suggestions, or motivations need not always be written references but may be found within the knowledge and creativity of ordinarily skilled artisans."

Here, even a flexible TSM test is failed because there simply is no motivation to make the combinations that the Examiner has proposed. Even assuming that the various components of Applicant's invention can be found (which we contest) in the three prior art patents now relied on, their assembly into Applicant's invention does not follow automatically. As the Supreme Court said in KSR: ". . . a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art."

Applicant submits that the claims as now presented clearly distinguish its invention over the prior art and requests that for all of the reasons presented above, and in light of the amendments to the claims, they be allowed.

Respectfully Submitted,

Dated 1.27.09

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A sheet filter 36 overlays the vent 23 at the interior surface 21 of lid 22 and is secured there by a generally planar filter cover 37 which has a pattern of cover holes 38 (cover vent) that are offset from vent holes 24 (Fig. 4) when cover 37 is mounted and locked in position ~~at by~~ posts 39 ~~by a and~~ locking mechanism 40 (filter cover mounts and locking mechanism). Mechanisms for locking a filter cover to a vent using slots or aligning posts such as posts 39 and establishing positive pressure on the cover against the vent are well known in the art and therefore require no further description.

Please replace second paragraph on page 5 with the following paragraph:

As best seen in Fig. 5, when the vent cover 37 is locked in position over the vent 23 by a filter cover mounting and locking mechanism 39 and 40 with a sheet filter 36 therebetween (the sheet filter 36 is sized to extend over and cover the vent recess 36), the cover ridge 43 is forced against vent recess 26 with a positive pressure, causing filter 36 and gasket 27 to be compressed together between lid 23 and cover 37, establishing a fluid-tight seal surrounding the vent ~~23 and cover vent 38~~. The gasket 27 in the vent recess 26 is critical to the fluid-tight seal and must be undamaged to be an effective barrier against contamination.

Please replace the paragraph beginning at page 5, line 20, with the following paragraph:

While the recess 26 and ridge 43 may be approximately equal in size, the filter 36 and the gasket 27 between the two causes a space 46 to be established therebetween when the cover 37 is fully engaged. This